

resulting in an improper process claim. Also, the Patent Office rejects Claims 1-10 under 35 U.S.C. §112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In addition, the Patent Office rejects Claims 1-10 under §102(b) as being anticipated by U.S. Patent No. 4,427,658 (*Maubois et al.*). The Patent Office also rejects Claims 1-10 under §102(b) as being anticipated by *Rooyackers et al.* (Clinical Nutrition, Vol. 14, No. 2, pp. 105-115, 1995). Applicants respectfully submitted that, in view of the amendments to the application and for the reasons set forth below, the objections and rejections have either been overcome or are improper and should be withdrawn.

In the Office Action, the Patent Office objects to the title of the invention as not being descriptive. In response, Applicants have amended the title as indicated above. Applicants believe that the title as amended is clearly indicative of the invention to which the claims are directed. If the Patent Office believes a different title is more appropriate, Applicants request that the patent office so advise Applicants' undersigned attorney.

The Patent Office states that the application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b) on a separate page. Applicants note that this Application did contain an abstract, however not on separate page. In response, Applicants have provided an abstract of the disclosure which is attached hereto on a separate sheet.

The Patent Office requests that trademarks or tradenames mentioned in the application be capitalized. Applicants believe that all trademarks or tradenames recited in the application have been capitalized. To the extent the Patent Office believes that there are any trademarks or tradenames, that are not capitalized, Applicants request that the Patent Office point out same.

The Patent Office objects to Claims 8-10 under 37 CFR 1.75(c) as being in improper form. The Patent Office asserts that Claims 8-10 are multiple dependent claims which should refer to other claims only in the alternative. Applicants have amended Claims 8-10 and added Claims 11-16 to properly depend from independent Claims 1, 2, and 3. Applicants believe that the amendments to the claims overcome this objection and the objection should be withdrawn.

The Patent Office rejects Claims 1-10 under 35 U.S.C. §101 alleging that Applicants claim a recitation of a use without setting forth any steps involved in a process, resulting in an improper process claim. Applicants have amended the claims to define methods having a step in which a composition including whey protein, or a protein mixture which simulates the amino acid profile of whey protein, is administered to a mammal. Therefore, Applicants respectfully submit that the rejection under 35 U.S.C. §101 is overcome and should be withdrawn.

Also, the Patent Office rejects Claims 1-10 under 35 U.S.C. §112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More specifically, the Patent Office alleges that the claims recite a use without any positive steps delimiting how the use is practiced. The Patent Office also alleges that the reference to "a protein mixture" in Claims 1-3 is indefinite. Further, the Patent Office alleges that the syntax of Claim 7 is unclear.

Applicants have amended independent Claims 1-3 to define methods which include a step of administering to a mammal a composition including whey protein, or a protein mixture which simulates the amino acid profile of whey protein. These amendments clearly point out and distinctly claim the subject matter of the invention in that a positive step is recited in each of the independent method claims. In addition, Applicants assert that the phrase "a protein mixture which simulates the amino acid profile of whey protein" is understood by those skilled in the art

to refer to a mixture of proteins, protein hydrolyzates and/or free amino acids which have the same or similar amino acid composition as whey protein. Thus, no further clarification is required for this portion of independent Claims 1-3.

Applicants note with respect to Claim 7 that this Claim does not recite three different ranges in one claim, but defines a concise weight distribution of the hydrolyzed whey. More specifically, the hydrolyzed whey is comprised of free amino acids and different types of peptides. The peptides are categorized by their molecular weight. Claim 7 merely defines weight percentages for the free amino acids and the different types of peptides within the hydrolyzed whey. For example, 15 to 55% by weight of the peptides have a molecular weight of less than 1000 DA and 20 to 55% have a molecular weight of 1000 to 5000 DA. Providing such ranges is how one skilled in the art defines the content of oligo- and polypeptides in a protein on protein hydrolyzate composition. Moreover, the weight distributions provided are not indefinite or confusing because the protein sources which may be utilized in the present invention are listed in the specification (page 3, line 34 to page 4, line 3) and the molecular weights for these protein sources are easily ascertainable. Therefore, Applicants request that the rejection under 35 U.S.C. §112, second paragraph should be withdrawn.

With respect to prior art, the Patent Office rejects Claims 1-10 under §102(b) as being anticipated by U.S. Patent No. 4,427,658 (*Maubois et al.*). The Patent Office also rejects Claims 1-10 under §102(b) as being anticipated by *Rooyackers et al.* (Clinical Nutrition, Vol. 14, No. 2, pp. 105-115, 1995). Applicants submit for the reasons set forth below that the rejection is not proper.

Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. *Lindemann Maschinenfabrik*

GmbH v. American Hoist & Derrick Co., 221 USPQ 481, 485 (Fed. Cir. 1984). There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Research Foundation v. Genentech Inc.*, 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991).

Maubois relates to a whey hydrolyzate and a process for producing same. The whey hydrolyzate is used for nutritional applications.

Rooyackers relates to the study of whether a diet containing a protein source rich in glutamine can restore depleted glutamine pools. In the study, the protein source included wheat protein hydrolyzate and a whey protein isolate. Wheat contains “more Glutamine than any other protein” and “35% of the amino acids residues are glutamine.” It was concluded that a diet containing a glutamine-rich protein source (wheat protein, as opposed to whey protein) can be used to increase plasma and muscle glutamine concentrations.

The present invention relates to a method for providing glutamine to, or increasing glutamine levels within, an individual using whey protein. Surprisingly, Applicants discovered that glutamine concentrations in a mammal may be increased by administering a composition to the mammal including whey protein, or a protein mixture simulating the amino acid profile of whey protein. The discovery is surprising in that whey protein itself contains little to moderate levels of glutamine. Thus surprisingly, an individual consuming less glutamine, but who consumes glutamine in the form of whey, will have a higher overall glutamine concentration upon consumption than an individual who consumes more glutamine in another form. See, Example 2 of Applicants’ patent application. The cited references fail to disclose or suggest Applicants’ surprising results.

Maubois is not concerned with glutamine. *Maubois* does not mention the importance of glutamine in the treatment of stressed mammals. Nor does *Maubois* mention the role of glutamine in muscle formation. *Maubois* also does not mention the role of glutamine in treating a mammal suffering from injured, diseased or under-developed intestines. *Maubois* does not mention the administration of whey protein for the purpose of increasing serum glutamine levels.

Maubois mentions the elevated contents of certain amino acids; however, glutamine is not one of the amino acids disclosed as being elevated. Clearly, *Maubois* does not disclose a method for providing glutamine to, or increasing glutamine levels within, a mammal, let alone the patient populations of independent claims 1 and 3 by administering a composition including whey protein, or a protein mixture simulating the amino acid profile of whey protein. Thus, *Maubois* does not anticipate the pending claims.

Rooyackers is concerned with the use of glutamine-rich protein sources to provide glutamine, as evidenced by the use of wheat hydrolyzate. However, the present invention discloses the use of whey protein or a protein mixture which simulates the amino acid profile of whey protein, either of which contains little to moderate levels of glutamine. Again, it is the surprising discovery that administration of a composition having whey protein or a like source can increase glutamine levels in a mammal that clearly distinguishes the present invention from *Rooyackers* wherein wheat protein is used because of its high level of glutamine. Thus, *Rooyackers* does not disclose each and every element of the claimed inventions.

Accordingly, Applicants respectfully submit that none of the references cited by the Patent Office disclose each and every claimed element of Applicants' invention. Applicants surprisingly discovered, that a protein source that has a low level of glutamine, whey, can

increase glutamine levels. The cited references fail to disclose or even arguably suggest this concept. Therefore, Applicants request that the rejections under §102 should be withdrawn.

Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

In the Title: Methods for ~~Providing~~ Increasing Glutamine Levels In a Mammal

In the Claims:

1. ~~The use of~~ A method for increasing plasma glutamine concentration in a stressed mammal, the method comprising the step of administering to the stressed mammal a nutritional composition including a protein source chosen from the group consisting of whey protein, or a protein mixture which simulates the amino acid profile of whey protein, ~~as a protein source in the preparation of a enterally administrable nutritional composition for increasing plasma glutamine concentration in a stressed mammal.~~
2. ~~The use of~~ A method for increasing muscle glutamine concentrations in a mammal, the method comprising the step of administering to the mammal a nutritional composition including a protein source chosen from the group consisting of whey protein, ~~or~~ and a protein mixture which simulates the amino acid profile of whey protein, ~~as a protein source in the preparation of a enterally administrable nutritional composition for increasing muscle glutamine concentrations in a mammal.~~
3. ~~The use of~~ A method for providing glutamine to a mammal suffering from injured, diseased or under-developed intestines, the method comprising the step of administering to the mammal a nutritional composition including a protein source chosen from the group consisting of whey protein, ~~or~~ and a protein mixture which simulates the amino acid profile of whey protein, ~~as a protein source in the preparation of a enterally administrable nutritional composition for providing glutamine to a mammal suffering from injured, diseased or under-developed intestines.~~

4. ~~The use according to claim 3 in which~~ The method of Claim 3 wherein the mammal is a pre-term infant having an under-developed intestine.

5. ~~The use according to claim 4 in which~~ The method of Claim 4 wherein the whey protein is hydrolyzed and the protein source further comprises arginine, tyrosine and histidine.

6. ~~The use according to claim 1 in which~~ The method of Claim 1 wherein the whey protein is hydrolyzed whey protein.

7. ~~The use according to claim 6 in which~~ The method of Claim 6 wherein the hydrolyzed whey protein contains less than about 5% by weight of free amino acids, about 15% to about 55% by weight of peptides having a molecular weight of less than 1000 Da, about 20% to about 55% by weight of peptides having a molecular weight of 1000 Da to 5000 Da, and about 15% to about 35% by weight of peptides having a molecular weight of greater than 5000 Da.

8. ~~The use according to any of claims in which the protein source~~ The method of Claim 1 wherein the protein source provides about 10% to about 20% of the energy of the nutritional composition.

9. ~~The use according to any of claims 1 to 3 in which~~ The method of Claim 1 wherein the nutritional composition further includes a lipid source which provides about 20% to about 50% of the energy of the nutritional composition, the lipid source comprising a mixture of medium chain and long chain fatty acids.

10. ~~The use according to any of claims 1 to 3 in which~~ The method of Claim 1 wherein the nutritional composition further includes a carbohydrate source which provides about 35% to about 65% of the energy of the nutritional composition.

Claims 11-19 have been added.